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THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP
600 GALLERIA PARKWAY, S.E.
STE 1500
ATLANTA, GA 30339-5994

EXAMINER	
TANNER, JOCELIN C	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,783	PAGANON, PASCAL	
	Examiner	Art Unit	
	JOCELIN C. TANNER	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2005* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The restriction requirement mailed on 18 April 2008 has been withdrawn. Claims 17-36 will be examined.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 20 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 20, the recitation "with the exception of zones acting as interfaces with devices fitted to the at least one flexible bag" renders the claim vague and indefinite since no zones or additional devices have been claimed.

4. Regarding claim 36, recitation "sufficient for protecting the balloon against gamma radiation" renders the claim vague and indefinite since undue experimentation is required to determine the concentration's sufficiency.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 17-18, 20-23, 27-29, 32, 33, 35, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuyava (US Patent No. 6,558,315).

3. Regarding claim **17**, Kuyava discloses a penile prosthesis or "intra-gastric balloon" including an expandable and inflatable cylinder or "flexible bag" (18) having inside and outside surfaces coated with parylene (column 5, lines 1-5, FIG. 1).

4. Regarding claims 17-26, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

5. Regarding claim **18**, Kuyava discloses a flexible bag (18) made of silicone (column 5, lines 1-2).

6. Regarding claim **20**, Kuyava discloses a flexible bag (18) having an entire outer surface coating of parylene (column 5, lines 40-41).

7. Regarding claims **21 and 22**, Kuyava discloses a coating thickness of 00004"-.00008" (1.016μm to 2.032μm) that is within the range of 0.2μm to 100μm and 1μm to 50μm.

8. Regarding claim **23**, Kuyava discloses a flexible bag (18) having a pump and valve assembly (14) that facilitates the expansion and contraction of the flexible bag in which pressurized fluid retreats or enters the bag for deflation or inflation (column 4, lines 50-54, FIG. 1).

9. Regarding claim **27**, Kuyava discloses a method of fabricating including the steps of depositing a coating of parylene on a portion of a surface of an inflatable bag (18) having and inside and outside surface (column 5, lines 1-5).

10. Regarding claim **28**, Kuyava discloses a method of depositing a coating of parylene on a flexible bag (18) by using a vapor deposition chamber (column 7, lines 3-10).

11. Regarding claim **29**, Kuyava discloses the method of fabricating a flexible bag (18) of silicone, a flexible, rubber-like material (column 4, lines 54-55).

12. Regarding claims **32, 33, 35 and 36**, Kuyava discloses the method of coating a flexible balloon (18) with a protective coating of polymer, i.e. parylene, the outer surface of the balloon (column 5, lines 1-5).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over de Kuyava (US Patent No. 6,558,315) in view of Yan (US Patent No. 6,287,277).

Regarding claim **19**, Kuyava fails to explicitly disclose a coating of parylene C.

Yan teaches inflatable members having a film of parylene C vacuum deposited on the surface of the balloon.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the parylene coating of the flexible bag of Kuyava with the parylene C film as taught by Yan, for the predictable result of providing a smooth exterior and reducing friction.

3. **Claims 17, 18, 20-26 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US Patent No. 5,361,752), in view of Kuyava (US Patent No. 6,558,315).**

Regarding claim **17**, Moll et al. discloses at least one expandable and inflatable cylinder or "flexible bag" (5) having inside and outside surfaces (FIG. 1). However, Moll fails to disclose a flexible bag coated with parylene.

Kuyava teaches a penile prosthesis or "intra-gastric balloon" including an expandable and inflatable cylinder or "flexible bag" (18) having inside and outside surfaces coated with parylene (column 5, lines 1-5, FIG. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the flexible bag of Moll et al. with the parylene coating, as taught by Kuyava, for the predictable result of providing the flexible bag with a frictionless, wear resistant, and leak proof exterior to eliminate ruptures that occur with frequent inflation and deflation.

4. Regarding claim **24**, Moll et al. discloses a second inflatable chamber or "second flexible bag"(25) disposed within the first inflatable chamber or "first flexible bag" (5) (column 8, lines 20-22, FIG. 1).

5. Regarding claim **25**, Moll et al. discloses a third inflation tube or "second fluid source" (35) used to expand the second bag (column 9, lines 67-68, column 10, lines 1-2, FIG. 1, elements #25, 35).

6. Regarding claim **31**, Moll et al. discloses the method step of using a flexible balloon (5) within the abdomen (column 8, lines 24-25).

7. Regarding claim **26**, Kuyava teaches a double wall structure of expandable tubes or "flexible bags" (18) having a parylene coating on both inner and outer surfaces of each flexible bag (18) (column 5, lines 14-16, column 7, lines 20-27). Therefore, this method step is rendered obvious by the above discussion.

8. Regarding claim **18**, Kuyava teaches a flexible bag (18) made of silicone (column 5, lines 1-2).

9. Regarding claim **20**, Kuyava teaches a flexible bag (18) having an entire outer surface coating of parylene (column 5, lines 40-41).

10. Regarding claims **21 and 22**, Kuyava teaches a coating thickness of 00004"-.00008" (1.016μm to 2.032μm) that is within the range of 0.2μm to 100μm and 1μm to 50μm.

11. Regarding claim **23**, Kuyava teaches a flexible bag (18) having a pump and valve assembly (14) that facilitates the expansion and contraction of the flexible bag in which

pressurized fluid retreats or enters the bag for deflation or inflation (column 4, lines 50-54, FIG. 1).

12. **Claims 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuyava (US Patent No. 6,558,315) in view Lafont et al. (US Patent No. 5,957,975).**

13. Regarding claims 30 and 33, Kuyava fails to disclose the method step of sterilizing the balloon through the use of gamma radiation.

Lafont et al. teach a system including a stent, catheter and balloon that are sterilized by the standard procedure of gamma radiation (column 8, lines 39-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have sterilized the balloon of Kuyava, using gamma radiation, as taught by Lafont et al., because it was a standard procedure to purify medical devices before their introduction into the body.

14. **Claims 17, 20, 23, 27, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al. (US Patent No. 4,694,827), in view Goldsteen et al. (US Patent No. 5,976,178).**

15. Regarding claim **17 and** the method of claim **31**, Weiner et al. discloses a flexible balloon (2) that is insertable within the stomach and has inside and outside surfaces (FIG. 1). However, Weiner et al. fails to disclose a coating of parylene.

Goldsteen et al. teach the application of coatings to attain biocompatibility and a high degree of smoothness which includes parylene (column 19, lines 44-54).

Since Weiner et al. and Goldsteen et al. teach known devices, i.e. expandable, flexible devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the balloon of Weiner et al. with a parylene coating, as taught by Goldsteen et al., because it was well known in the art to provide lubricious coatings to medical devices to achieve biocompatibility, distensibility and a degree of smoothness.

16. Regarding claim **23**, Weiner et al. discloses a flexible bag (2) having a self-sealing hole (7) through which a hollow pin (9) is introduced into an insufflation tube used to inflate the balloon (column 3, lines 17-21).

17. Regarding claim **20**, Goldsteen et al. teach the application of parylene to the entire surface including the inside and outside surface of a device (column 19, lines 40-43).

18. Regarding claims **27 and 28**, Goldsteen et al. discloses a method of fabricating including the steps of vapor depositing a coating of parylene on a portion of a device having and inside and outside surface (column 20, lines 47-49).

19. The method steps of claims **27, 28 and 31** are rendered obvious by the above discussion.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. De la Torre et al (US Patent No. 7,033,373), Gannoe et al (US Patent No. 6,746,460) and Chan et al (US Patent No. 5,993,473) are related to expandable devices within a patient's body cavity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
6/26/2008
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731